

Applicant : Tuo Jin  
U.S. Serial No.: 10/606,344  
Filed : June 25, 2003  
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REMARKS

Claim Status

Claims 1-19 were under examination in the application. Claims 1-19 have been canceled without prejudice to Applicant's right to pursue the subject matters in a future application and new claims 20-38 have been added. New claims 20-38 are fully supported by the originally filed specification. Therefore, there is no issue of new matter. Applicant respectfully requests the entry of this Amendment.

Claim Objections

The disclosure is objected to because of the following informalities: the word "phospholipids" on page 8, line 16 is spelled with an unnecessary hyphen as "phospho-lipid" and the word "triamterene" is misspelled on the 1<sup>st</sup> line of Example 4 as "triamteren."

In response, Applicant has hereinabove amended the specification according to suggestions of the Examiner to whom this application is assigned. Accordingly, this issue has been corrected.

Claims 2, 5, 7, 10, and 11 are objected to because of informalities.

In response, but without conceding the correctness of the Examiner's position and to expedite the prosecution of this application, Applicant has hereinabove cancelled claims 2, 5, 7, 10, and 11 without prejudice, therefore rendering the ground of rejection moot.

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Rejection Under 35 U.S.C. §112

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In response, but without conceding the correctness of the Examiner's position and to expedite the prosecution of this application, Applicant has hereinabove cancelled claim 11 without prejudice, therefore rendering the ground of rejection moot.

Rejection Under 35 U.S.C. §102

The Examiner rejected claims 1-9, 12-13, and 16-19 under 35 U.S.C. 102(e) as being anticipated by Pather et al. (U.S. Patent No. 6,280,770; IDS reference) as evidenced by K. Y. Yang et al. ("Effects of Amorphous Silicon Dioxides on Drug Dissolution," *Journal of Pharmaceutical Sciences*, 1979, 68(5), 560-565).

The Examiner further rejected claims 1, 3, and 8-11 under 35 U.S.C. 102(b) as being anticipated by K. Y. Yang et al ("Effects of Amorphous Silicon Dioxides on Drug Dissolution," *Journal of Pharmaceutical Sciences*, 1979, 68(5), 560-565).

In response, Applicant respectfully traverse the above ground of rejection. Specifically, Applicant does not agree with the Examiner's points: "this property (absorbing lipids in the melt state) is inherent to silicon dioxide,..." page 7, line 11-12 of this Office Action, Applicant would like to point out:

A) Drug-lipid mixtures loaded in the porous powders are not

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necessarily to form an emulsion when added in an aqueous medium. That is why Pather et al. needed to pre-formulate the drug and lipids to an emulsion prior to absorbing them into the powders. Applicant demonstrated a method by which pre-formulation of an emulsion is not necessary;

- B) In the case that Pather et al. and Yang et al. have to prepare their compounds and lipids into emulsions, the volume of the solvents (the continuous phases of emulsions) is much larger than the dispersed phase (the direct drug vehicle). This limits the drug loading significantly. Drug loading capacity is especially important for insoluble or poorly soluble drugs because considerable amount of lipids have to be used. However, in Pather et al. and Yang et al.'s methods, the drug or drug and lipids have to be further diluted by the solvents. Applicant's claimed invention, does not require said solvent. The entire volume of the pores of the powder can be used to absorb drugs and lipids. See example in Exhibit A (1 page).

Accordingly, in view of the previous discussion, Applicant respectfully requests the reconsideration and withdrawal of this ground of rejection.

#### Conclusion

Applicant respectfully maintain that all the grounds of rejections raised in the September 19, 2006 Office Action have

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been addressed and earnestly urge the Examiner to render favorable action for the claimed invention.

If a telephone interview would be of assistance in advancing the prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below. If any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

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